IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA
DURHAM DIVISION

SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI Plaintiffs, v. ACCORD HEALTHCARE, INC. Defendant.	Civil Action No. 1:15-cv-18

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Sanofi-Aventis U.S. LLC (hereinafter "Sanofi U.S."), Aventis Pharma S.A. (hereinafter "Aventis") and Sanofi (collectively, "Plaintiffs") for their Complaint against defendant Accord Healthcare, Inc. (hereinafter "Accord" or "Defendant"), hereby allege as follows:

THE PARTIES

1. Plaintiff Sanofi U.S. is a U.S. subsidiary of Sanofi and is a company organized and existing under the laws of the State of Delaware, having commercial headquarters at 55 Corporate Drive, Bridgewater, New Jersey 08807.

2. Plaintiff Aventis is a corporation organized and existing under the laws of France, having its principal place of business at 20 avenue Raymond Aron, 92160 Antony, France.

3. Plaintiff Sanofi is a corporation organized and existing under the laws of France, having its principal place of business at 54 rue La Boétie, 75008 Paris, France.

4. Plaintiff Sanofi is a global research-driven pharmaceutical company that discovers, develops, manufactures and markets a broad range of innovative products to improve human and animal health.

5. On information and belief, defendant Accord is a corporation organized and existing under the laws of North Carolina, having its principal place of business at 1009 Slater Road, Suite 210B, Durham, North Carolina 27703.

6. On information and belief, Accord is a wholly-owned subsidiary of Intas Pharmaceuticals Ltd. (hereinafter "Intas"). On information and belief, Intas is a corporation organized under the laws of India, with its principal place of business at 2nd Floor, Chinubai Centre, Off. Nehru Bridge, Ashram Road, Ahmedabad 380009, Gujarat, India.

ACCORD ANDA

7. On information and belief, Accord assembled and caused to be filed with the United States Food and Drug Administration ("FDA"),

Abbreviated New Drug Application ("ANDA") No. 207693 pursuant to 21 U.S.C. § 355(j) (§ 505(j) of the Federal Food, Drug and Cosmetic Act) (hereinafter "the Accord ANDA") concerning a proposed drug product, Cabazitaxel Injection, 60 mg/1.5 mL (hereinafter "Accord's Proposed ANDA Product").

ACCORD B2 NDA

8. On information and belief, Accord assembled and caused to be filed with the FDA, New Drug Application ("NDA") No. 207949 pursuant to 21 U.S.C. § 355(b)(2) (§ 505(b)(2) of the Federal Food, Drug and Cosmetic Act) (hereinafter "the Accord B2 NDA") concerning a proposed drug product, Cabazitaxel Injection, 20 mg/mL, 3 mL (hereinafter "Accord's Proposed B2 Product").

JURISDICTION AND VENUE

9. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

10. This Court has personal jurisdiction over Accord. On information and belief, Accord is a corporation organized and existing under the laws of North Carolina, having its principal place of business at 1009 Slater Road, Suite 210B, Durham, North Carolina 27703. On information and belief, Accord

maintains a corporate agent for the service of process at 1009 Slater Road, Suite 210B, Durham, North Carolina 27703.

11. On information and belief, Accord directly or through its alter ego, affiliates and agents develops, formulates, manufactures, markets, imports and sells pharmaceutical products, including generic drug products, which are copies of products invented and developed by innovator pharmaceutical companies, throughout the United States, including in this Judicial District. On information and belief, Accord is the holder of Registration No. 380 active drug manufacturer license with the North Carolina Department of of Agriculture and Consumer Services.

12. On information and belief, "Accord has been servicing the needs of the US healthcare industry since 2009," and its "business in the USA . . . currently accounts for more that [sic] USD 100 million in revenue." Accord Healthcare, Global Presence – USA site available at http://www.accord-healthcare.com/global-presence-usa.html (last visited December 11, 2014). On information and belief, Accord is "the preferred supplier for leading distributors and retail pharma chains" in the United States. Intas, International Operations, USA site available at http://www.intaspharma.com/index.php?option=com_content&view=article&id=56&Itemid=63 (last visited December 11, 2014).

13. On information and belief, Accord has previously submitted to the jurisdiction of this Court and have availed themselves of the legal protections of the State of North Carolina, having asserted counterclaims in this jurisdiction, including in the matters of *The Medicines Co. v. Accord Healthcare, Inc. et al.*, Civil Action No. 1:14-cv-00626 (TDS)(JLW), Docket No. 19 at 3, 9-16 (M.D.N.C. Sep. 26, 2014); *Hospira, Inc. et al. v. Intas Pharmaceuticals Ltd. et al.*, Civil Action No. 1:14-cv-00336 (NCT)(JLW), Docket No. 12 at 3, 8-11 (M.D.N.C. Apr. 28, 2014); and *Eli Lilly Co. v. Accord Healthcare, Inc. et al.*, Civil Action No. 1:11-cv-00261 (UA)(LPA), Docket No. 17 at 1, 4-7 (M.D.N.C. Dec. 12, 2011).

14. On information and belief, Accord has affiliations with the State of North Carolina that are pervasive, continuous, and systematic. On information and belief, Accord engages in direct marketing, distribution, and/or sale of generic pharmaceutical drugs within the State of North Carolina and to the residents of the State of North Carolina, and maintenance of corporate agents in the State of North Carolina.

15. On information and belief, Accord regularly conducts and solicits business in the State of North Carolina, engages in other persistent courses of conduct in the State of North Carolina, and/or derives substantial revenue from services or things used or consumed in the State of North Carolina.

16. Accord is also subject to personal jurisdiction in the State of North Carolina because, *inter alia*, Accord has committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271(e)(2) that has led and/or will lead to foreseeable harm and injury to Plaintiffs. By letter dated November 24, 2014 ("November 24 ANDA Notice Letter"), Accord notified Plaintiffs that it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("ANDA Paragraph IV Certification") with respect to U.S Patent No. 5,847,170 ("'170 patent"). By letter dated November 25, 2014 ("November 25 B2 Notice Letter"), Accord notified Plaintiffs that it had filed a certification pursuant to 21 U.S.C. §355(b)(2)(A)(iv) ("B2 Paragraph IV Certification") with respect to the '170 patent. In its November 24 ANDA Notice Letter, Accord states that it intends to engage in the manufacture, use, and/or sale of Accord's Proposed ANDA Product before the expiration of the '170 patent throughout the United States, including in this Judicial District. In its November 25 B2 Notice Letter, Accord states that it intends to engage in the manufacture, use, and/or sale of Accord's Proposed B2 Product before the expiration of the '170 patent throughout the United States, including in this Judicial District.

17. On information and belief, upon approval of the Accord ANDA, Accord and/or its affiliates or agents will market, sell and/or distribute

Accord's Proposed ANDA Product throughout the United States, including in this Judicial District, and will derive substantial revenue therefrom.

18. On information and belief, upon approval of the Accord ANDA, Accord and/or its affiliates or agents will place Accord's Proposed ANDA Product into the stream of commerce with the reasonable expectation or knowledge and the intent that such product will ultimately be purchased and used by consumers in this Judicial District.

19. On information and belief, upon approval of the Accord B2 NDA, Accord and/or its affiliates or agents will market, sell and/or distribute Accord's Proposed B2 Product throughout the United States, including in this Judicial District, and will derive substantial revenue therefrom.

20. On information and belief, upon approval of the Accord B2 NDA, Accord and/or its affiliates or agents will place Accord's Proposed B2 Product into the stream of commerce with the reasonable expectation or knowledge and the intent that such product will ultimately be purchased and used by consumers in this Judicial District.

21. Venue is proper in this Court at least pursuant to 28 U.S.C. §§ 1391(b), (c), and/or (d), and 1400(b).

THE PATENT-IN-SUIT

22. Sanofi U.S. holds approved New Drug Application ("NDA") No. 201023 for cabazitaxel injection, 60 mg/ 1.5 mL (40 mg/mL), which is prescribed and sold in the United States under the trademark JEVTANA® KIT (hereinafter "JEVTANA®"). The U.S. Food and Drug Administration ("FDA") approved NDA No. 201023 on June 17, 2010. JEVTANA® is approved for use in combination with prednisone for the treatment of patients with hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing treatment regimen.

23. United States Patent No. 5,847,170 (the "'170 patent," copy attached as Exhibit A) is entitled "Taxoids, Their Preparation And Pharmaceutical Compositions Containing Them" and was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on December 8, 1998. The '170 patent claims, *inter alia*, cabazitaxel and pharmaceutical compositions containing cabazitaxel. The '170 patent is listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") for JEVTANA® (NDA No. 201023).

24. The '170 patent is owned by Aventis.

CLAIMS FOR RELIEF – PATENT INFRINGEMENT BY ACCORD ANDA

25. On information and belief, Accord submitted the Accord ANDA to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Accord's Proposed ANDA Product.

26. On information and belief, the Accord ANDA seeks FDA approval of Accord's Proposed ANDA Product for use in combination with prednisone for the treatment of patients with hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing treatment regimen.

27. On information and belief, Accord actively participated in and/or directed activities related to the submission of the Accord ANDA and the development of Accord's Proposed ANDA Product, was actively involved in preparing the Accord ANDA, and/or intends to directly benefit from and has a financial stake in the approval of the Accord ANDA. On information and belief, upon approval of the Accord ANDA, Accord will be involved in the manufacture, distribution, and/or marketing of Accord's Proposed ANDA Product.

28. In its November 24 ANDA Notice Letter, Accord notified Plaintiffs that it had submitted to the FDA the Accord ANDA, seeking approval to engage in the commercial manufacture, use, or sale of Accord's Proposed ANDA Product before the expiration of the '170 patent, and that it had filed an ANDA Paragraph IV Certification with respect to the '170 patent. The November 24 ANDA Notice Letter was received by Plaintiffs on November 26, 2014.

29. On information and belief, in its November 24 ANDA Notice Letter, Accord certified that the ’170 patent is invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of Accord’s Proposed ANDA Product.

30. The Accord ANDA refers to and relies upon the Sanofi U.S.’s NDA No. 201023 for JEVTANA®.

CLAIMS FOR RELIEF – PATENT INFRINGEMENT BY ACCORD B2 NDA

31. On information and belief, Accord submitted the Accord B2 NDA to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Accord’s Proposed B2 Product.

32. On information and belief, the Accord B2 NDA seeks FDA approval of Accord’s Proposed B2 Product for use in combination with prednisone for the treatment of patients with hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing treatment regimen.

33. On information and belief, Accord actively participated in and/or directed activities related to the submission of the Accord B2 NDA and the development of Accord’s Proposed B2 Product, was actively involved in preparing the Accord B2 NDA, and/or intends to directly benefit from and has a financial stake in the approval of the Accord B2 NDA. On information and belief,

upon approval of the Accord B2 NDA, Accord will be involved in the manufacture, distribution, and/or marketing of Accord's Proposed B2 Product.

34. In its November 25 B2 Notice Letter, Accord notified Plaintiffs that it had submitted to the FDA the Accord B2 NDA, seeking approval to engage in the commercial manufacture, use, or sale of Accord's Proposed B2 Product before the expiration of the '170 patent and that it had filed a B2 Paragraph IV Certification with respect to the '170 patent. The November 25 B2 Notice Letter was received by Plaintiffs on December 1, 2014.

35. On information and belief, in its November 25 B2 Notice Letter, Accord certified that the '170 patent is invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of Accord's Proposed B2 Product.

36. The Accord B2 NDA refers to and relies upon the Sanofi U.S.'s NDA No. 201023 for JEVTANA®.

COUNT I

INFRINGEMENT OF U.S. PATENT NO. 5,847,170 BY ACCORD ANDA

37. Plaintiff repeats and realleges paragraphs 1 through 36 above as if fully set forth herein.

38. By submitting the Accord ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of Accord's Proposed ANDA Product throughout the United States

prior to the expiration of the ’170 patent, Accord committed an act of infringement of the ’170 patent under 35 U.S.C. § 271(e)(2). On information and belief, Accord was aware of the ’170 patent at the time the Accord ANDA was submitted.

39. If Accord commercially makes, uses, offers to sell, or sells Accord’s Proposed ANDA Product within the United States, or imports Accord’s Proposed ANDA Product into the United States, or induces or contributes to any such conduct during the term of the ’170 patent, it would further infringe the ’170 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

40. Plaintiffs will be irreparably harmed if Accord is not enjoined from infringing the ’170 patent. Plaintiffs do not have an adequate remedy at law.

41. Accord’s certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the ’170 patent was wholly unjustified, and thus this case is exceptional under 35 U.S.C. § 285.

COUNT II

INFRINGEMENT OF U.S. PATENT NO. 5,847,170 BY ACCORD B2 NDA

42. Plaintiff repeats and realleges paragraphs 1 through 41 above as if fully set forth herein.

43. By submitting the Accord B2 NDA under 21 U.S.C. § 355(b)(2) for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of Accord’s Proposed B2 Product throughout the United

States prior to the expiration of the ’170 patent, Accord committed an act of infringement of the ’170 patent under 35 U.S.C. § 271(e)(2). On information and belief, Accord was aware of the ’170 patent at the time the Accord B2 NDA was submitted.

44. If Accord commercially makes, uses, offers to sell, or sells Accord’s Proposed B2 Product within the United States, or imports Accord’s Proposed B2 Product into the United States, or induces or contributes to any such conduct during the term of the ’170 patent, it would further infringe the ’170 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

45. Plaintiffs will be irreparably harmed if Accord is not enjoined from infringing the ’170 patent. Plaintiffs do not have an adequate remedy at law.

46. Accord’s certification under 21 U.S.C. § 355(b)(2)(A)(iv) against the ’170 patent was wholly unjustified, and thus this case is exceptional under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that Accord Healthcare, Inc. has infringed one or more claims of the ’170 patent by filing ANDA No. 207693 relating to Accord’s Proposed ANDA Product before the expiration of the ’170 patent;

B. A judgment that Accord Healthcare, Inc. has infringed one or more claims of the ’170 patent by filing NDA No. 207949 relating to Accord’s Proposed B2 NDA Product before the expiration of the ’170 patent;

C. A judgment that the manufacture, use, offer for sale, sale and/or importation of Accord’s Proposed ANDA Product and/or Accord’s Proposed B2 NDA Product will infringe the ’170 patent;

D. A judgment declaring that the ’170 patent remains valid and enforceable;

E. A permanent injunction restraining and enjoining Accord Healthcare, Inc., and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Accord’s Proposed ANDA Product and/or Accord’s Proposed B2 NDA Product until the expiration of the ’170 patent or any later date of exclusivity to which Plaintiffs and/or the ’170 patent are or become entitled to;

F. An order that the effective date of any approval of Accord’s ANDA No. 207693 relating to Accord’s Proposed ANDA Product under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(j)) shall be a date that is not earlier than the expiration date of the ’170 patent or any later date of exclusivity to which Plaintiffs and/or the ’170 patent are or become entitled;

G. An order that the effective date of any approval of Accord's NDA No. 207949 relating to Accord's Proposed B2 Product under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(b)(2)) shall be a date that is not earlier than the expiration date of the '170 patent or any later date of exclusivity to which Plaintiffs and/or the '170 patent are or become entitled;

H. A declaration that this case is "exceptional" within the meaning of 35 U.S.C. § 285 and an award of reasonable attorney fees, costs, expenses, and disbursements of this action; and

I. Such other and further relief as the Court may deem just and proper.

January 7, 2015

Respectfully submitted,

/s/ James L. Lester
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